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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/731,068	12/08/2003	Thomas J. Maginot	22220-08641	6619

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EXAMINER	
PREBILIC, PAUL B	

ART UNIT	PAPER NUMBER
3738	

DATE MAILED: 10/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/731,068	MAGINOT, THOMAS J.	
	Examiner	Art Unit	
	Paul B. Prebilic	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 August 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *See Continuation Sheet* is/are pending in the application.

4a) Of the above claim(s) *6-84 and 202-259* is/are withdrawn from consideration.

5)☒ Claim(s) *5,131,133,138,139,260 and 261* is/are allowed.

6)☒ Claim(s) *See Continuation Sheet* is/are rejected.

7)☒ Claim(s) *121* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *8/1/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Continuation of Disposition of Claims: Claims pending in the application are 1,4-86,90-92,97-99,101-103,105,110-112,114,119,121-123,127-129,131,133,138,139,141,146,153-155,157,162,169-171,173,175,182-184,186,191,193-195,198-200,202-261 and 263.

Continuation of Disposition of Claims: Claims rejected are 1,4,85,86,90-92,97-99,101-103,105,110-112,114,119,122,123,127-129,141,146,153-155,157,162,169-171,173,175,182-184,186,191,193-195,198-200 and 263.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on July 28, 2005 has been entered.

Election/Restrictions

Claims 6-84 and 202-259 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions, there being no allowable generic or linking claim.

Applicant's election of Group I in the reply filed on February 3, 2005 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP 818.03(a)).

Claim Objections

Claim 195 is objected to because of the following informalities:

Regarding claim 195, on line 2, "the arteriotomy" lacks antecedent basis. The Examiner suggests changing "the arteriotomy" to ---an arteriotomy--- in order to overcome this objection. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 193 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 193 depends upon cancelled claim 192, and thus, its scope cannot be determined. For this reason, the Examiner will not evaluate it on its merits.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1 and 4 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 5 of copending Application No. 10/726,803 in view of Redtenbacher et al (US 4,817,847). Although the conflicting claims are not identical, they are not patentably distinct from each other because the copending claims are narrower in scope than the present claims but are read on by the present claims except for the "endoscopic" instrument

use as claimed herein. However, Redtenbacher teaches that endoscopic use during similar anastomosis procedures was known; see column 3, lines 16-25 and the paragraph bridging columns 6 and 7. Therefore, it is the Examiner's position that it would have beep obvious to use an endoscope in the procedure of the copending claims for the same reasons that Redtenbacher uses the same and in order to perform the procedure with greater accuracy and precision.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim 1 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of copending Application No. 10/824,043 in view of Redtenbacher et al (US 4,817,847). Although the conflicting claims are not identical, they are not patentably distinct from each other because the copending claims are narrower in scope than the present claims but are read on by the present claims except for the "endoscopic" instrument use. However, Redtenbacher teaches that endoscopic use during similar anastomosis procedures was known; see column 3, lines 16-25 and the paragraph bridging columns 6 and 7. Therefore, it is the Examiner's position that it would have been obvious to use an endoscope in the procedure of the copending claims for the same reasons that Redtenbacher uses the same and in order to perform the procedure with greater accuracy and precision.

Claim Rejections Based Upon Prior Art

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 85, 86, 91, 114, 128, 129, 141, 157, 170, and 171 are rejected under 35 U.S.C. 102(e) as being anticipated by Kaster (US 5,234,447). Kaster anticipates the claim language where the locating step as claimed is the step of inserting the blood vessel into the mandrel of Kaster (see column 2, lines 63-68), the blood conveying vessel as claimed is the blood vessel (51) of Kaster, the advancing step as claimed is shown in Figures 14-19 of Kaster, and the vessel as claimed is the second vessel of Kaster; see column 6, line 5 to column 7, line 20. The removing step as claimed is disclosed on column 7, lines 8-14.

Claims 101-103, 105, 110-112, and 123 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kaster (US 5,234,447) alone. Kaster meets the claim language

as explained *supra*, but does not disclose using the method thereof specifically on an aorta. However, since Kaster is a generic method of attaching blood vessels in an anastomosis, it is the Examiner's position that it would have been considered *prima facie* obvious to utilize the method of Kaster to anastomize an aorta based upon the need of a patient to have a bypass of a portion of the aorta. Since the Kaster device can be utilized on any blood vessel, it is reasonable that it could be utilized on an aorta as well if the same condition from bypass are present as those disclosed by Kaster; see column 1.

Claims 90, 92, 97-99, 119, 122, 127, 146, 153-155, 162, 169, 173, 175, 182-184, 186, 191, 194, 195, 198, 199, and 200 are rejected under 35 U.S.C. 1O3(a) as being unpatentable over Kaster (US 5,234,447) in view of Palmaz (US 4,733,665). Kaster meets the claim language except for the structure of having the conduit end or the entire conduit within the delivery device as claimed. However, Palmaz teaches that it was known to deliver similar grafts to blood vessels via catheters; see column 1, lines 20-30. Therefore, it is the Examiner's position that it would have been obvious to use a catheter over the mandrel and staple of Kaster for the same reasons that Palmaz does the same and in order to protect the staple, mandrel, sleeve, and the bypass blood vessel prior to and during the procedure.

Claim 263 is rejected under 35 U.S.C. 102(e) as being anticipated by Wilk (US 5,261,861). Wilk anticipates the claim language where the medical instrument as claimed is the catheter (20) of Wilk and the heart wall of Wilk is construed to be outside

the blood vessel; see Figures 3A to 3E, 4, and Figures 5A to 6C as well as columns 3 to 5.

Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kaster (US 5,234,447) in view of Redtenbacher et al (US 4,817,847) or Avant (US 5,047,039). Kaster meets the claim language as explained above but fails to disclose the use of an endoscope or laparoscope during the process as claimed. However, Redtenbacher teaches that endoscopic use during anastomosis procedures was known; see column 3, lines 16-25 and the paragraph bridging columns 6 and 7. Likewise, Avant teaches laparoscopic anastomosis was known; see the title and abstract. Therefore, it is the Examiner's position that it would have been obvious to use a endoscope or laparoscope in the Kaster procedure so that it could have been performed with greater accuracy and precision due to the greater visibility of the site.

Allowable Subject Matter

Claim 121 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 5, 131, 133, 138, 139, 260, and 261 are allowed over the prior art of record.

Response to Arguments

Applicant's arguments filed July 28, 2005 have been fully considered but they are not persuasive.

For the most part, the claims have been amended or have been rejected with other grounds. However, the arguments on page 54 of the July 28, 2005 response are not persuasive because all the limitations are seen as being present in Kaster. In particular, the second or proximal end of the graft or conduit of Kaster is advanced relative to the opening as the mandrel is removed therefrom after it has been attached to the second blood vessel; see column 7, lines 11-14.

In response to applicant's arguments against the Kaster, Redtenbacher, and Avant references individually as they are used in the Section 103 rejection, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.,* 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Conclusion

Applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 USC 102 of 35 USC 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is respectfully requested to provide a list of all copending applications that set forth similar subject matter to the present claims. A copy of such copending claims is respectfully requested in response to this Office action if the application is not stored in image format (i.e. the IFW system) or published.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Paul B. Prebilic whose telephone number is (571) 272-4758. He can normally be reached on 6:30-5:00 M-Th.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, McDermott Corrine can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Paul Prebilic
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Art Unit 3738